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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,326	08/30/2001	Martin Gleave	UBC.P-020-2	2324
<div>57381      7590      09/04/2007 Marina Larson &amp; Associates, LLC P.O. BOX 4928 DILLON, CO 80435</div>				
			<div>EXAMINER VIVLEMORE, TRACY ANN</div>	
			<div>ART UNIT 1635</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 09/04/2007</div>	<div>DELIVERY MODE PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

09/944,326

Applicant(s)

GLEAVE ET AL.

Examiner

Tracy Vivlemore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 12-15, 19, 24-26, 29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 19 and 30 is/are rejected.
- 7) ☒ Claim(s) 12-15, 24-26 and 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 6/19/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to arguments: Double Patenting*

Claims 1, 19 and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,900,187 in view of McKay et al. and Cowsert (both of record). This rejection is maintained for the reasons set forth in the office action mailed March 19, 2007.

Applicants traverse the double patenting rejection by arguing the Examiner has offered no reasons why any term extension would be unjust in this case, nor any reason why it would be a burden on the art to allow separate patents to issue without a requirement for common ownership, asserting that the statement of the general rationale for requiring a terminal disclaimer even in 20-year term cases which bridges Pages 7 and 8 of the official action is not a substitute for an explanation of why the rejection should be applied in this case. As explained in the previous office action, in the instant case there is no question of extending patent term since both applications claim priority to the same date and any patent issuing from the instant application will expire on the same date as the '187 patent. Also, a terminal disclaimer contains a provision that any patent granted on that application be enforceable only for and during the period that the patent is commonly owned with the application or patent which formed the basis for the rejection, which serves to avoid the potential for harassment of an accused infringer by multiple parties with patents covering the same patentable invention. The reason why the rejection should be applied in this case was also

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provided; if the owner of this application were to receive two patents covering the claimed subject matter and they were sold separately the new owners could not only harass anyone accused of infringement but could potentially sue each other for infringement.

Applicants reiterate previous arguments regarding the prosecution of the '187 patent and repeat their arguments that the claims in the later application have been determined to be patentably distinct by an examiner of the USPTO, based on the content of the claims and not on the common inventorship or ownership of the patent. Based on this argument applicants conclude the double-patenting rejection as made in the present application places an inventor who improves his own prior work in a worse position than a stranger who made the same improvement and continues to assert the examiner is questioning the validity of the '187 patent. Applicants also assert at several points that this rejection questions the validity of the '187 patent. These arguments were addressed at pages 9-11 of the previous office action and are not repeated here.

Applicants traverse the rejection by arguing the secondary references cited in the rejection have nothing to do with the claimed sequence and do not disclose modifications at the specific locations within this sequence. Applicants further argue the techniques as reflected in the references would not lead to the structures claimed in the '187 patent, stating that the assertion of "mere design choice" is not a substitute for a showing that the result of a design effort would have been obvious. Applicants further argue the possibilities for making modifications to a nucleic acid sequence of 21 bases are essentially endless and the structure as claimed is merely one among many options

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and there is not suggestion of using the particular structure with this particular sequence. Applicants arguments and the discussion of prior art regarding size of gaps within antisense sequences affecting efficacy appear to be arguing that there is a lack of motivation of combining the teachings of the cited references in order to arrive at the claimed invention. These arguments are not persuasive because the statement that use of 5-methylcytosines at any particular position or combination of positions represents mere design choice is not a substitution for showing the patented claims are an obvious variation of the instant claims, it is the reason the claims are an obvious variation. Based on the teaching in the instant specification that oligonucleotides can be modified to improve stability *in vivo*, including the explicit recitation of phosphorothioate and 2'-methoxyethyl modifications and the teachings of the prior art of the gapmer substitution motif, the person of ordinary skill in the art would find it an obvious design choice to combine these teachings and arriving at the claimed substitution pattern is a matter of routine optimization.

***Allowable Subject Matter***

Claims 12-15, 24-26 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz, can be reached on 571-272-0763. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your

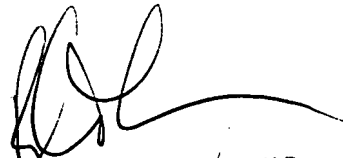
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application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore  
Examiner  
Art Unit 1635

TV  
March 14, 2007



RICHARD SCHNIZER, PH.D.  
PRIMARY EXAMINER